



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Note to Reader
September 9, 1998

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply, EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, if unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

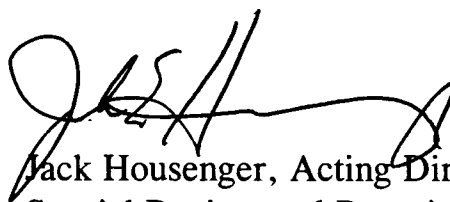
There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues

available in the information in this docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

A handwritten signature in black ink, appearing to read 'J. Housenger', with a long horizontal flourish extending to the right.

Jack Housenger, Acting Director
Special Review and Reregistration
Division

April 29, 1998

ADDENDUM MEMORANDUM

SUBJECT: Ethoprop (041101). Anticipated Residues for Chronic
(Cancer) Dietary Exposure.
MRID None. DP Barcode D245524.

FROM: Sheila Piper, Chemist
Chemistry & Exposure Branch 1 (CEB-1)
Health Effects Division (7509C)

THROUGH: Francis B. Suhre, Branch Senior Scientist
Chemistry & Exposure Branch 1 (CEB-1)
Health Effects Division (7509C)

TO: Kit Farwell, D.V.M.
Reregistration Branch 1
Health Effects Division (7509C)

Action Requested

Generate anticipated residue estimates to assess chronic (cancer) dietary risk for ethoprop in support of the Reregistration Eligibility Decision Document (J.Abbotts, 3/23/98).

Residue Information

Tolerances for residues of ethoprop in/on plant RACs are currently expressed in terms of ethoprop per se [40 CFR 180.262 (a) and (b)]. No food/feed tolerances have been established for residues of ethoprop. Adequate methods are available for the enforcement of established tolerances, as currently defined.

The HED Metabolism Committee recently determined the residues to be regulated are parent

ethoprop (O-ethyl-S,S-dipropylphosphorodithioate) plus metabolites designated as Metabolite II (O-ethyl-S-methyl-S-propylphosphorodithioate), Metabolite III (O-ethyl-O-methyl-S-propyl phosphorothioate), and Metabolite IV (O-ethyl-S-propylphosphorothioate) (see memo of J.Abbotts, 10/29/96). However, submitted magnitude of the residue studies contained only the parent or parent and Metabolite IV; studies accepted by the FRSTR reported data on parent only (10/20/87). According to the Residue Chemistry Chapter of the ethoprop RED (J. Abbotts, 3/23/98), tolerances will be reassessed based on combined residues of parent and metabolite IV and making conservative assumptions regarding levels of metabolites II and III using data from the metabolism studies.

The HED Metabolism Committee found that for acute and chronic (non-cancer) dietary risk, the residues of concern in crops are parent and metabolites II and III; for cancer dietary risk, residues of concern are parent and metabolites II through IV (J.Abbotts 10/29/96).

Dietary Exposure

To account for all metabolites of concern for cancer risk identified by the HED metabolism committee (parent + metabolites II, III, and IV), data from ethoprop metabolism and crop rotation studies were used to derive residue adjustment factors by dividing residues of (parent + metabolites II, III, and IV) by residues of (parent + metabolite IV). These adjustment factors were then used to convert data from residue field trials (parent + metabolite IV) to anticipated residues reflecting the total residue of concern (parent + metabolites II, III, and IV). Adjustment factors ranged from 1.0x to 5.3x with the average being 2.1x (see Tables 1-5).

Table 1: Ethoprop and metabolites of concern in corn.

Residue	Forage:		Fodder:	
	%TRR	ppm	%TRR	ppm
Ethoprop	7.8	0.17	0.5	0.01
Metabolite II. O-ethyl-S-methyl-S-propylphosphorodithioate	0.3	0.01	1.1	0.02
Metabolite III. O-ethyl-O-methyl-S-propylphosphorothioate	0.8	0.02	1.8	0.03
Metabolite IV. O-ethyl-S-propylphosphorothioate	2.3	0.05	0.8	0.01
Total Residues of Concern for Cancer (Ethoprop + Met II + III + IV)	11.2	0.25	4.2	0.07
Sum of Ethoprop + Metabolite IV	10.1	0.22	1.3	0.02
Ratio of Total Residues of Concern to Ethoprop + Metabolite IV (ppm)	1.1X		3.5X	

Table 2: Ethoprop and metabolites of concern in cabbage

Metabolite	Cabbage leaves		Cabbage heads	
	%TRR	ppm	%TRR	ppm
Ethoprop	4.0	0.62	0.8	0.02
Metabolite II. O-ethyl-S-methyl-S-propylphosphorodithioate	0.6	0.09	0.4	0.01
Metabolite III. O-ethyl-O-methyl-S-propylphosphorothioate	1.7	0.26	1.7	0.05
Metabolite IV. O-ethyl-S-propylphosphorothioate	2.5	0.39	0.3	0.01
Total Residues of Concern for Cancer (Ethoprop + Met II + III + IV)	8.8	1.36	2.9	0.09
Sum of Ethoprop + Metabolite IV	6.5	1.01	1.1	0.03
Ratio of Total Residues of Concern to Ethoprop + Metabolite IV (ppm)	1.3X		3.0X	

Table 3: Summary of characterized/identified residues in radish roots rotated from aged sandy loam soil treated with [¹⁴C]ethoprop at 1x the maximum seasonal rate for annual crops.

Metabolite	31-DAT		123-DAT	
	%TRR	ppm	%TRR	ppm
I. Ethoprop	7.6	0.33	5.1	0.07
II. O-ethyl-S-methyl-S-propylphosphorodithioate	0.3	0.01	--	--
III. O-ethyl-O-methyl-S-propylphosphorothioate	0.2	0.01	--	--
IV. O-ethyl-S-propylphosphorothioate	21.0	0.91	--	--
Total Residues of Concern for Cancer (Ethoprop + Met II + III + IV)	29.1	1.26	--	--
Sum of Ethoprop + Metabolite IV	28.6	1.24	--	--
Ratio of Total Residues of Concern to Ethoprop + Metabolite IV (ppm)	1.0X		----	

Table 4: Table 4: Summary of characterized/identified residues in/on spinach rotated from aged sandy loam soil treated with [¹⁴C]ethoprop at 1x the maximum seasonal rate for annual crops.

Metabolite	31-DAT	
	%TRR	ppm
I. Ethoprop	0.4	0.08
II. O-ethyl-S-methyl-S-propylphosphorodithioate	1.8	0.34
III. O-ethyl-O-methyl-S-propylphosphorothioate	---	---
IV. O-ethyl-S- propylphosphorothioate	---	---
Total Residues of Concern for Cancer (Ethoprop + Met II + III + IV)	2.2	0.42
Sum of Ethoprop + Metabolite IV	0.4	0.08
Ratio of Total Residues of Concern to Ethoprop + Metabolite IV (ppm)	5.3X	

Table 5: Summary of characterized/identified residues in/on wheat rotated from aged sandy loam soil treated with [¹⁴C]ethoprop at 1x the maximum seasonal rate for annual crops.

Metabolite	31-DAT		123-DAT	
	%TRR	ppm	%TRR	ppm
Wheat Forage				
I. Ethoprop	6.5	1.82	4.9	0.25
II. O-ethyl-S-methyl-S-propylphosphorodithioate	0.8	0.22	--	--
III. O-ethyl-O-methyl-S-propylphosphorothioate	0.3	0.08	--	--
IV. O-ethyl-S- propylphosphorothioate	--	--	10.5	0.53
Total Residues of Concern for Cancer (Ethoprop + Met II + III + IV)	7.6	2.12	15.4	0.78
Sum of Ethoprop + Metabolite IV	6.5	1.82	15.4	0.78

Ratio of Total Residues of Concern to Ethoprop + Metabolite IV (ppm)	1.2X		1.0X	
Wheat Straw				
I. Ethoprop	1.3	0.62	0.3	0.13
II. O-ethyl-S-methyl-S-propylphosphorodithioate	--	--	0.05	0.02
III. O-ethyl-O-methyl-S-propylphosphorothioate	0.6	0.27	0.4	0.16
IV. O-ethyl-S- propylphosphorothioate	--	--	0.2	0.09
Total Residues of Concern for Cancer (Ethoprop + Met II + III + IV)	1.9	0.89	0.95	0.40
Sum of Ethoprop + Metabolite IV	1.3	0.62	0.5	0.22
Ratio of Total Residues of Concern to Ethoprop + Metabolite IV (ppm)	1.4X		1.8X	

Table Note: DAT= days after treatment for planting. See Table 7 for structures.

Summary

The average residues from field trial data reflect residues of parent and metabolite IV. Residues reported as none detected ND (LOD=0.002 ppm) were adjusted to one-half the LOD (0.001 ppm). The maximum residues from field trial data were taken from the highest residues found on the crop at the 1x rate. The average adjustment factor is 2.1 and the maximum adjustment factor is 5.3 (see Tables 1-5). Chronic anticipated residues were calculated from the average residues from field trial data multiplied by the average adjustment factor. Acute anticipated residues were calculated from the maximum residues from field trial data multiplied by the maximum adjustment factor. The HED Risk Assessor conducting the DRES analysis should be advised that the Chronic AR and Acute AR in Table 6 are not corrected for percent crop treated.

Table 6: Ethoprop Anticipated Residues for Acute and Chronic Non-Cancer Dietary Exposure

RAC	Food Items	Tolerance		Average Residues from Field Trial Data ³	Average Adjustment Factor ⁴	Chronic (Cancer) Anticipated Residues ⁵	% Crop Treated ⁶
		Established ¹	Pending ²				
Bananas		0.02	0.04	0.04	2.1	0.084	100.0*
Beans, Lima		0.02	0.02	0.004	2.1	0.008	4.00
Beans, Snap		0.02	0.2	0.030	2.1	0.063	4.00
Cabbage		0.02	0.05	0.034	2.1	0.071	1.00
Corn, Sweet		0.02		0.001	2.1	0.002	2.00
Corn, Grain	starch, refined oil, grits, meal & flour	0.02		0.001	2.1	0.002	2.00
Cucumbers		0.02	0.1	0.047	2.1	0.099	1.00
Peanuts(nutmeat)		0.02		0.065	2.1	0.137	2.00
	meal			0.001	2.1	0.002	2.00
	oil, refined			0.012	2.1	0.025	2.00
Pineapples		0.02	0.02	0.02	2.1	0.042	100.0*
	juice			0.02	2.1	0.042	100.0*
Potatoes		0.02		0.001	2.1	0.002	7.00
	granules/flakes, chips peel, wet			0.001	2.1	0.002	7.00

RAC	Food Items	Tolerance		Average Residues from Field Trial Data ³	Average Adjustment Factor ⁴	Chronic (Cancer) Anticipated Residues ⁵	% Crop Treated ⁶
		Established ¹	Pending ²				
Sugarcane		0.02		0.001	2.1	0.002	5.00
	molasses, sugar refined			0.001	2.1	0.002	5.00
Sweet Potatoes		0.02		0.001	2.1	0.002	15.00

¹ 40CFR 180.262: Tolerance established on parent only.

² Tolerance are reassessed for parent + Metabolite IV (See RED section 18).

³ Data from field trial data: Average of (parent + Metabolite IV). Residues reported as ND (LOD=0.002) were adjusted to one-half LOD (0.001).

⁴ The ratio of the [parent + Metabolite II + III + IV] / [parent + Metabolite IV] from Metabolism studies and Crop Rotation studies. The average adjustment factor is 2.1 and the maximum adjustment factor is 5.3.

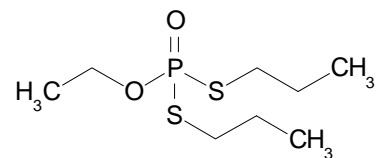
⁵ Chronic (cancer) AR: Average residues from field trial data multiply by average adjustment factor. Values were not corrected for % crop treated.

⁶ BEAD (4/11/95) supplied the estimates of % crop treated.

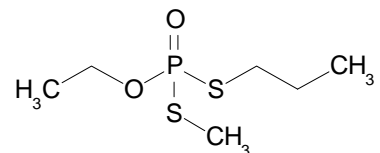
* 100% crop treated was assumed in the absence of % crop treated.

Table 7: Ethoprop and metabolites identified in primary and rotational crops.

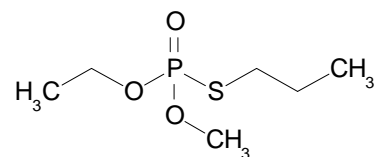
I. O-ethyl-S,S-dipropylphosphorodithioate; ethoprop



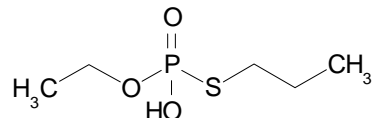
II. O-ethyl-S-methyl-S-propylphosphorodithioate



III. O-ethyl-O-methyl-S-propylphosphorothioate



IV. O-ethyl-S-propylphosphorothioate



cc: Spiper, RF, SF, Reg Std File

RDI: ResChem Team: 4/21/98: ChemSac Mtg: 4/23/98: FBSuhre: 4/29/98

7509C:CEB1:SPiper:CM-2:Rm 718D: 308-2717: Ethoprop

DP BARCODE: D245524

DATA PACKAGE RECORD
BEAN SHEET

DATE: 04/28/98
Page 1 of 1

* * * FREE STANDING DATA PACKAGE * * *

THERE IS NO CASE OR SUBMISSION DATA

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 245524 EXPEDITE: N DATE SENT: 04/28/98 DATE RET.: / /
CHEMICAL: 041101 Ethoprop
DP TYPE: 999

	CSF: N		LABEL: N		
ASSIGNED TO	DATE	IN	DATE	OUT	ADMIN DUE DATE: / /
DIV : HED	/	/	/	/	NEGOT DATE: / /
BRAN: CEB1	/	/	/	/	PROJ DATE: / /
SECT: IO	/	/	/	/	
REVR : SPIPER	/	/	/	/	
CONTR:	/	/	/	/	

* * * DATA REVIEW INSTRUCTIONS * * *

Prepare anticipated residue estimates for conducting a dietary cancer risk assessment.

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

THERE ARE NO ADDITIONAL DATA PACKAGES

9049
(a)